Calendar No. 703

101ST CONGRESS
2d Session

SENATE

REPORT
101-380

BREAST AND CERVICAL CANCER MORTALITY PREVENTION ACT OF 1990

JULY 19 (legislative day, JULY 10), 1990.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 2283]

CONTENTS

	Page
I. Summary of the bill	1
II. Background and need for the legislation	2
III. Hearings	5
IV. Text of the bill	7
V. Committee actions	13
VI. Cost estimate	14
VII. Regulatory impact statement	15
VIII. Section-by section analysis	15
IX. Committee views	21
X. Additional views	25
XI. Changes in existing law	26

I. SUMMARY OF THE BILL

The purpose of S. 2283 is to establish a new Title within the Public Health Service Act to authorize grants to States to carry out programs to provide preventive screening and referral services for breast and cervical cancer and to support other public health activities related to the detection and control of these diseases.

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II. Background and Need for the Legislation

BACKGROUND

Each year, both breast and cervical cancer kills thousands of American women. In 1989 alone, there were an estimated 142,000 new cases of breast cancer and 43,000 deaths associated with the disease. In that same year, approximately 13,000 new cases of invasive cervical cancer were reported and some 6,000 females died as a result of such a diagnosis. For the decade of the 1990's, it is projected that more than 500,000 American women will lose their lives to these two diseases, a disproportionately large number of whom will be low-income. These rates can be reduced significantly, however, through the use of early detection technologies, accurate diagnoses, and appropriate follow-up medical treatment.

Breast cancer and mammograms

Breast cancer is the most common cancer to strike American women, accounting for more than 25 percent of all female cancers. At the present rate, one of every 10 women in this country will develop breast cancer during her lifetime. Typically, the disease is one that affects older women. But when it does hit younger women, the illness tends to be more aggressive. Indeed, today, breast cancer is the leading cause of death in females under age 65; and among black women, nearly two-thirds who die from breast cancer are under this age.

The cause of breast cancer remains unknown. And because the source is not yet understood, the disease cannot be prevented. In recent years, however, great advances have been made in the management of breast cancer. Nonetheless, no available therapy is capable of curing the disease once it has become widespread.

As with so many other life-threatening illnesses, early detection of breast cancer is the key to its control. For example, the five-year survival rate for women with localized breast cancer can be almost 100 percent. This rate drops dramatically, however (to 18 percent) for women with disease that has spread to other sites in the body. Treatment at this later stage is not only more debilitating; it is also much less effective.

Today, the detection technology of choice among medical professionals, cancer specialists, and public health experts alike is mammography. In brief, mammography is an X-ray procedure used to visualize the internal structure of the breast. Because it is capable of detecting non-palpable cancers (cancers too small to be felt), it complements a physical examination of the breasts for women who have no symptoms. In addition, comparison of a current mammogram with an earlier one may reveal subtle changes in the breast that may signal cancer. Mammography can also provide information helpful to the diagnosis of a breast abnormality in females who have symptoms such as a lump or thickening. The procedure is used to monitor for cancer reoccurrence as well. Overall, the diagnostic accuracy of mammography, in combination with a physical examination of the breasts, may be greater than 90 percent. Periodic use of the procedure can lower a woman's risk of dying from breast cancer by 30 percent.

Because of mammography's accuracy in finding disease and its effectiveness in reducing mortality, both the National Cancer Institute and the American Cancer Society recommended that women receive a baseline mammography between ages 35 and 40, followed by annual or biennial mammograms from ages 40 to 49; and annual mammograms beginning at age 50. These guidelines have been endorsed by other health organizations such as the American Medical Association, the American College of Obstetricians and Gynecologists, and the American College of Radiology. Substantially similar recommendations have been made by the U.S. Preventive Services Task Force in its 1989 report, "Guide to Clinical Preventive Services."

Despite the demonstrated efficacy of mammography and the promulgation of formal guidelines, the overall utilization of the technology is extremely low. According to a January 1990 study by the General Accounting Office (GAO), "Screening Mammography: Low-Cost Services Do Not Compromise Quality" (GAO-HRD-90-32), approximately 60 percent of women age 40 and over have never had a screening mammogram. The proportion of females receiving regular screens is even considerably less. Women with lower incomes and less education are least likely to receive this preventive health measure. In 1987, for example, only 9.2 percent of women with family incomes of less than $10,000 had had a mammogram during the previous year.

There are a number of reasons women give for not being screened. Some (12 percent of white women and 29 percent of black women age 40 and over) have never heard of mammography. Others fear that a malignancy might be found. But the most common explanations are that women do not think they need to have a mammography and that their physicians have not recommended the procedure. The Centers for Disease Control have reported that, as a result of such attitudes, of women 50 years or older who saw a physician in the last year, only 29 percent said that they had received a mammogram within that same time period.

The high costs of, and the lack of coverage, for, mammography also act as deterrents. The GAO found in its "Screening Mammography" study that the fees charged for screening mammography can range from $50 or less to over $150, with an average charge of $104. Today, only 29 States require third-party private insurance coverage for such costs. The Medicare Program offers no help to elderly and disabled women. (The Program was to have included a new mammography benefit effective in 1990, but that protection was lost when the Medicare Catastrophic Coverage Act of 1990 was repealed (Public Law 101-234) last year.) And there is little evidence that States through their Medicaid programs have provided any assistance to poor women. (To date, only Rhode Island's Medicaid program has been identified by the Subcommittee as providing coverage for screening mammograms.)

Cervical cancer and pap smears

Cancer of the uterin cervix—or cervical cancer—accounts for almost 3 percent of all cancers in American women today. Although females are most at risk of getting cervical cancer between

the ages of 45 and 50, they are susceptible to this disease at any time between their late teens and old age.

While the precise cause of cervical cancer in still unknown, several risk factors have been associated with the disease, including early onset of sexual intercourse, a history of multiple sex partners, and low socioeconomic status. Women who do not engage in sexual intercourse are not at significant risk of cervical cancer. However, no certain method for preventing the disease now exists; nor is there any certain method for curing the disease once it has become widespread.

Like breast cancer, cancer of the cervix can be controlled if it is found early on. Today, the five-year survival rate stands at about 90 percent for women with localized cervical cancer. It is considerably lower, however, (about 40 percent), for those with advanced disease. But treatment of the cancer at its later stages is usually quite drastic and often very ineffective in preventing further progression of the disease.

For some 40 years now, the Papanicolaou—or "Pap"—smear has been recognized as the universal screening tool for cervical cancer in asymptomatic women. The test consists of a sample of cells, scraped or aspirated from the cervix, affixed to a glass slide. The sample is derived from the thin layer of cells on the surface of the cervix that is continually being shed in the normal day-to-day process of cellular growth and aging. It includes cells from the outer surface of the cervix, the inner cervix, and the transformation zone between. The slides are sent to a laboratory where they are examined and reports are prepared which indicate if there is any suspicion of disease. While the overall accuracy of the test continues to be debated, there is no doubt that the 70 percent decrease in cervical cancer deaths that has occurred over the last four decades is directly attributable to the use of Pap smears. Moreover, there is a general belief among public health experts that most of the 6,000 deaths that still occur each year could be prevented through regular Pap smear screening and appropriate follow-up treatment.

Although inconsistent guidelines of PAP testing have been issued in the past, a consensus recommendation has not been adopted by the National Cancer Institute, the American Cancer Society, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Nurses Association, the American Academy of Family Physicians, and the American Medical Women's Association. Their statement calls for annual Pap smears for all women who are or have been sexually active or have reached age 18. Testing is permitted less frequently once three or more annual smears have been normal and if recommended by the woman's physician. Similar recommendations have been made by the U.S. Preventive Task Force in its 1989 report, "Guide to Clinical Preventive Services."

While the Pap smear has become an accepted part of medical care practice and is widely available (94 percent of primary care physicians report that they perform the procedure), data from the Centers for Disease Control indicate that 52 percent of women have not been tested, within the last year. Moreover, women who are poor or older, or who are living in rural areas receive Pap smears less often than other women. Older women in particular may not

be tested because they believe their post-menopausal status has eliminated their risk for cervical cancer. Indeed according to the Office of Technology Assessment's (OTA) February 1990 study, "The Costs and Effectiveness of Cervical Cancer Screening in Elderly Women," only slightly more than half (52 percent) of elderly women have had a Pap smear within the last three years.

Unlike mammography screening, the reasons women choose to forgo a regular Pap smear test are not so easily defined. Most women are aware of the procedure's availability and effectiveness. A majority of them have even been tested by a physician at least once. But simply seeking medical care does not ensure that periodic screening will take place. According to one study cited by OTA in its "Cervical Cancer Screening" report, regularity and recency of Pap testing is closely associated with the type of health care provider seen—having a gynecologist as the usual source of care is linked with a greater probability of receiving regular Pap screens. Relatively few poor and older women, however, use a gynecologist on a regular basis as their primary provider of gynecological care.

The costs of the test and the limited third-part coverage that is available to help pay for it seem to be inhibiting factors as well. Although the fees associated with a Pap smear are not nearly as high as they are for mammography screening, they can be significant. OTA's own estimate, for example, of the combined cost of both the test itself as well as a short visit to a gynecologist, is approximately $43. Few States, however, are believed to require their private insurers to provide coverage for these costs. Medicare recently extended its benefit package to offer coverage for elderly and disabled women to have Pap smears, but only once every three years (Public Law 101-239). And Medicaid coverage for the test appears to be limited, making access to this preventive health care measure for poor women difficult, at best.

NEED FOR LEGISLATION

With the availability of mammograms and Pap smears, it is possible to reduce significantly the number of deaths that occur each year in American women from both breast and cervical cancer. This is particularly true for low-income women who are less likely to receive these services and who are more likely to die from these diseases. S. 2283 arises from a basic concern that for far too long, these goals have been out of reach.

Some States have tried to support cancer mortality prevention campaigns on their own. But their programs have been small and quite limited. Other States simply feel that they cannot afford to undertake such an effort and consistently place disease prevention programs on the bottom of their health care agenda.

To help those women who are not now served, it is clear that a targeted, well-coordinated effort—with contributions from both Federal and State government—must be supported. Although the primary purpose of such a policy must be to provide preventive breast and cervical cancer screening and referral services, public health experts agree that a successful program must also include activities directed at public education, health professional training,

quality control, and appropriate monitoring and surveillance mechanisms.

III. Hearing Summary

A hearing on Cancer Detection in Women was held by the Committee on Labor and Human Resources on January 28, 1988. The purpose of this hearing was to review procedures for cancer detection in women, focusing on mammography and the early detection of breast cancer, and problems in the medical testing industry concerning Pap smears. The following individuals provided testimony:

The Honorable Brock Adams, United States Senator, State of Washington.

The American Society of Clinical Pathologists, submitted prepared statement.

The Honorable Orrin G. Hatch, United States Senator, State of Utah, submitted prepared statement.

Jill Ireland, Honorary Chair, National Crusade, American Cancer Society, and submitted prepared statement.

Rose Kushner, Founder and Executive Director, Breast Cancer Advisory Center; Cofounder, National Alliance Cancer Advisory Board, and submitted prepared statement.

The Honorable Barbara A. Mikulski, United States Senator, State of Maryland, and submitted prepared statement.

Doctor Cyril A. Schulman, Clinical Professor of Medicine, George Washington University, Washington, DC, on behalf of the American Cancer Society, and submitted prepared statement.

Doctor Robert Hasselbrack, Director, Fifth Avenue Medical Center, Accu-Pap Diagnostic Services, Seattle, WA, and submitted prepared statement.

Patricia Ashton, President, Cell Diagnostics, Inc., Durham, NC, on behalf of the American Society of Cytotechnology, and submitted prepared statement.

Doctor Herbert Dickerman, Director, Wadsworth Center for Laboratories and Research, New York State Department of Health, Albany, NY, and submitted prepared statement.

The Honorable Paul Simon, United States Senator, State of Illinois, submitted prepared statement.

Doctor Charles R. Smart, Chief, Early Detection Branch, Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, Bethesda, MD, and submitted prepared statement.

Doctor Philip Strax, Clinical Professor of Oncology and Radiology, University of Miami School of Medicine, Miami, FL, and submitted prepared statement.

Doctor Dixie Melillo, Chairman, Department of Surgery, Pasadena Bayshore Medical Center, Houston, TX, and submitted prepared statement.

Lea Thompson, Investigative Reporter, Consumer Affairs Unit, WRC-TV, News 4, Washington, DC.

Barbara Arbuckle, Seattle, WA.

IV. Text of the Bill as Reported

[S. 2283; 101st Cong., 2d Sess.]

A BILL To amend the Public Health Service Act tc establish a program of grants for the prevention and control of breast and cervical cancer, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Breast and Cervical Cancer Mortality Prevention Act of 1990".

SEC. 2. ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES FOR PREVENTION AND CONTROL OF BREAST AND CERVICAL CANCER.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by inserting after title XIV the following new title:

"TITLE XV--PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

"SEC. 1501. ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES.

"(a) In General.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of carrying out programs—

"(1) to screen women for breast and cervical cancer as a preventive health measure;

"(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

"(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

"(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

"(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

"(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

"(b) Preferences in Making Grants.—In making grants under subsection (a), the Secretary shall give preference to any State in which—

"(1) there is a substantial rate of mortality associated with breast or cervical cancer (relative to the national rate of such mortality); and

"(2) there is an inadequate availability of services or activities described in such subsection.

"(c) GEOGRAPHIC DISTRIBUTION OF GRANTS.—In making grants under subsection (a), the Secretary shall ensure that the grants are equitably distributed among the principal geographic regions of the United States.

"(d) GRANT AND CONTRACT AUTHORITY OF STATES.—A State receiving a grant under subsection (a) may expend the grant to carry out the purpose described in such subsection through grants to, and contracts with, public or nonprofit private entities.

"SEC. 1502. REQUIREMENT OF MATCHING FUNDS.

"(a) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

"(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

"(1) IN GENERAL.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

"(2) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

"(3) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a).

"SEC. 1503. REQUIREMENTS WITH RESPECT TO TYPE AND QUALITY OF SERVICES.

"(a) REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.—The Secretary may not make a grant under section 1501 unless the State involved agrees—

"(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers;

"(2) subject to subsection (b), to ensure that—

"(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

"(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

"(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) is provided; and

"(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

"(b) USE OF IMPROVED SCREENING PROCEDURES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

"(c) QUALITY ASSURANCE REGARDING SCREENING FOR BREAST CANCER.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will assure the quality of any screening procedure for breast cancer conducted pursuant to such section and, in the case of mammography, will provide that—

"(1) the equipment used to perform the mammography will be specifically designed for mammography and will meet appropriate radiologic standards for mammography;

"(2) the mammography will be performed by an individual who—

"(A) is licensed by a State to perform radiological procedures; or

"(B) is certified as qualified to perform radiological procedures by an appropriate organization;

"(3) the results of the mammography will be interpreted by a physician who—

"(A) is certified as qualified to interpret radiological procedures by an appropriate board; or

"(B) is certified as qualified to interpret screening mammography procedures by an appropriate program for assuring the qualifications of the individual with respect to such interpretations; and

"(4) with respect to the first screening mammography performed on a woman for which payment is made pursuant to section 1501(a), there are satisfactory assurances that the results of the mammography will be placed in permanent medical records maintained with respect to the woman.

"(d) QUALITY ASSURANCE REGARDING SCREENING FOR CERVICAL CANCER.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will assure the quality of any screening procedure for cervical cancer conducted pursuant to such section and, in the case of the pap smear (or other

cytological screening procedure replacing the pap smear pursuant to subsection (b)), will provide—

"(1) the maximum number of cytology slides that any individual may screen in a 24-hour period;

"(2) requirements that a clinical laboratory maintain a record of—

"(A) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory; and

"(B) the number of hours devoted during each 24-hour period to screening cytology slides by such individual;

"(3) criteria for requiring rescreening of cytological preparations, such as—

"(A) random rescreening of cytology specimens determined to be in the benign category;

"(B) focused rescreening of such preparations in high risk groups; and

"(C) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available;

"(4) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions;

"(5) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides;

"(6) requirements that all cytological screening be done on the premises of an appropriately qualified laboratory;

"(7) requirements for the retention of cytology slides by laboratories for appropriate periods of time; and

"(8) requirements of periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

"(e) ISSUANCE BY SECRETARY OF GUIDELINES WITH RESPECT TO QUALITY OF MAMMOGRAPHY AND CYTOLOGICAL SERVICES.—

"(1) IN GENERAL.—The Secretary shall establish guidelines for assuring the quality of any mammography and cytological screening procedure conducted pursuant to section 1501(a). Such guidelines with respect to mammography shall include the provisions of paragraphs (1) through (4) of subsection (c), and such guidelines with respect to cytological screening procedures shall include the provisions of paragraphs (1) through (8) of subsection (d).

"(2) APPLICABILITY WITH RESPECT TO GRANTS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will, with respect to any mammography or cytological screening procedure conducted pursuant to such section, ensure that the procedure is conducted in accordance with the guidelines issued by the Secretary under paragraph (1).

"(3) RESPONSIBILITY OF STATES IN ABSENCE OF GUIDELINES.—With respect to circumstances in which a State receives a

grant under section 1501 before the issuance of guidelines under paragraph (1), this subsection may not be construed to affect in such circumstances the obligation of the State pursuant to subsection (a)(1) to provide for screening procedures and referrals or the obligations under subsections (c) and (d) with respect to providing for quality in the screening procedures.

"SEC. 1504. ADDITIONAL REQUIRED AGREEMENTS.

"(a) PRIORITY FOR LOW-INCOME WOMEN.—The Secretary may not make a grant under section 1501 unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a).

"(b) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

"(1) will be made according to a schedule of charges that is made available to the public;

"(2) will be adjusted to reflect the income of the woman involved; and

"(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

"(c) STATEWIDE PROVISION OF SERVICES.—

"(1) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(2) WAIVER.—The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a).

"(d) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

"(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

"(2) by an entity that provides health services on a prepaid basis.

"(e) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

"(f) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

"(g) RECORDS AND AUDITS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that—

"(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

"(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

"(h) REPORTS TO SECRETARY.—The Secretary may not make a grant under section 1501 unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

"SEC. 1505. DESCRIPTION OF INTENDED USES OF GRANT.

"The Secretary may not make a grant under section 1501 unless—

"(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

"(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a); and

"(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities.

"SEC. 1506. REQUIREMENT OF SUBMISSION OF APPLICATION.

"The Secretary may not make a grant under section 1501 unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505, and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title.

"SEC. 1507. TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

"(a) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

"(b) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

"(1) IN GENERAL.—Upon the request of a State receiving a grant under section 1501, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the

purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

"(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

"SEC. 1508. EVALUATIONS AND REPORTS.

"(a) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 1501.

"(b) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a), and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate.

"SEC. 1509. FUNDING.

"(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $50,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

"(b) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507.

"(c) LIMITATION ON NUMBER OF INITIAL GRANTS.—For fiscal year 1991, the Secretary may not make more than 15 grants under section 1501.".

V. COMMITTEE ACTION

S. 2283 was introduced on March 9, 1990 and referred to the Committee on Labor and Human Resources. This bill was considered by the Committee in Executive Session on June 27, 1990. Senator Mikulski offered a substitute amendment to the bill, and the bill as amended was reported favorably by unanimous voice vote.

VI. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, July 3, 1990.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2283, the Breast and Cervical Cancer Mortality Prevention Act of 1990, as ordered reported by the Senate Committee on Labor and Human Resources on June 27, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Robert D. Reischauer,
Director.

Attachment.

1. Bill number: S. 2283.
2. Bill title: Breast and Cervical Cancer Mortality Prevention Act of 1990.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on June 27, 1990.
4. Bill purpose: To amend the Public Health Service Act to establish a program of grants for the prevention and control of breast and cervical cancer, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels	50	52	54		
Estimated outlays	27	41	50	25	11

The costs of this bill fall within budget function 550.

Basis of Estimate

S. 2283 would authorize the Secretary of Health and Human Services (HHS) to grant funds to states to screen women for breast and cervical cancer; provide referrals for medical treatment to such women; develop and disseminate information for the prevention of breast and cervical cancer; improve the training of health professionals in the prevention of breast and cervical cancer; and monitor the quality of screening procedures for breast and cervical cancer. In addition, the Secretary of HHS would have to evaluate and report to Congress annually on the success of this grant program.

The bill authorizes $50 million in fiscal year 1991 and such sums as may be necessary for fiscal years 1992 and 1993 for these activities. CBO estimated the 1992 and 1993 authorization levels by increasing the 1991 authorization by projected inflation. This esti-

mate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: The bill would require states receiving grants to contribute to the cost of providing the preventive health services. The contribution amount would be not less than $1 of non-federal funds for each $3 of federal funds. Assuming that all of the grants authorized are appropriated and awarded, the states would have to contribute approximately $17 million in each of fiscal years 1991 and 1992, and $18 million in fiscal year 1993.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

VII. Regulatory Impact Statement

The Committee has determined that implementation of the provisions of this bill will produce a minimal amount of regulatory burden and paperwork. A program to prevent breast and cervical cancer mortality already exists within the CDC and those activities will continue on an expanded basis without need for increased regulation.

The quality standards established in S. 2283 reflect requirements that have been previously set in Federal law; this legislation does not seek to promulgate new regulations, and seeks to avoid any conflict in standards among Federal health programs involved with the early detection and prevention of cancer.

The Secretary is required to conduct evaluations and make reports to Congress annually summarizing progress made and making recommendations for the future.

VIII. Section-by-Section Analysis

SECTION 1—SHORT TITLE

Section 1 establishes the short title of the legislation to the "Breast and Cervical Cancer Mortality Prevention Act of 1990".

SECTION 2—ESTABLISHMENT OF PROGRAM

Section 2 establishes a new Title XV of the Public Health Service Act, entitled "Preventive Health Measures with Respect to Breast and Cervical Cancers."

SECTION 1501—ESTABLISHMENT OF PROGRAMS OF GRANTS TO STATES

Section 501 established a program of grants to be awarded to the States and to be administered by the Centers of Disease Control for the support of a number of public health activities related to the early detection and control of breast and cervical cancer.

Section 1501(a) establishes that the purpose of these grants is to assist States in carrying out a number of activities related to the early detection and control of breast and cervical cancer. These activities include (i) the provision of prevention screening services to

women for breast and cervical cancer; (ii) the provision of appropriate referrals for medical treatment for those women who receive a positive screen and to ensure, to the extent practicable, the provision of appropriate follow-up services; (iii) the development and dissemination of public information and education programs on the detection and control of breast and cervical cancer; (iv) the improvement of the education, training, and skills of health professionals in the detection and control of these diseases; (v) the establishment of State quality control mechanisms for monitoring breast and cervical cancer screening procedures; and (vi) the evaluation of each of these activities through appropriate surveillance or program-monitoring mechanisms.

As required under section 1503 (described below), States must, by the conclusion of the second year of a grant, provide all six of the activities cited above in (or through) their breast and cervical cancer mortality prevention programs. They must, however, throughout the entire period of a grant, provide both mammography and Pap smear services and appropriate referrals for required medical treatment. In addition, they must ensure, throughout the entire period of the grant, to the extent practicable, that women who need medical treatment as a result of a positive screen are, in fact, provided with such care.

Although the purpose of this Program is not to provide (or to support the provision of) medical treatment (such as surgical procedures or intensive chemotherapy requiring hospitalization) to women who are determined to be in need of such care as a result of a positive mammogram or Pap smear, these women should not go unserved. Further testing, if recommended, should be offered and provided; and all necessary steps should be taken to ensure that appropriate follow-up treatment is made available. Preventive screening technologies like mammography and the Pap smear cannot be promoted in good faith if access to these services cannot be assured. Grantees should take all appropriate measures to ensure the provision of any additional services required by women who receive a positive test result.

As to the provision of the preventive screening services themselves, evidence is presented in the previous part of this Report (Background and Need for Legislation) regarding the wide variation in, and the relatively high costs of, the fees charged for such services. According to the GAO report cited in that Section of this Report "Screening Mammography", high volume is essential for providing screening mammography at lower fees. (Presumably, this would be the case with screening Pap smears as well). States should conduct their cancer mortality prevention programs in such a manner as to focus their mammography and Pap smear screening activities in centers or facilities (such as public hospitals or mobile van units) that can provide a high volume of tests to the Program's targeted population at lower costs.

With respect to public education and information campaigns that are to be conducted under this Section, such efforts should include material on all three forms of gynecological cancers, including cervical, ovarian, and uterine (or endometrial) cancer. Discussions with experts indicate that there may be some confusion about the differences among these types of cancer and about the various

methods used to detect and treat each of them. (Pap smears are not, for example, used to screen for cancer of the ovaries.) A more broadly focused public education program will serve not only to help reduce the number of cervical cancer deaths among American women; it will also assist in lowering the death rates associated with other types of gynecological cancers.

Section 1501(b) requires that the Secretary, in making grants, give preference to any States in which (i) there is a substantial rate of mortality associated with breast or cervical cancer (relative to the national rate of such mortality); and (ii) there is an inadequate availability of the services or activities described in Section 1501(a).

Section 1501(c) requires that the Secretary, in making grants, ensure that the grants are equitably distributed among the principal geographic regions of the United States. Efforts shall be made to fund programs in both urban and rural States.

Section 1501(d) allows States, in carrying out their breast and cervical cancer mortality prevention programs, to award subcontracts (or other cooperative agreements) to public or non-profit private entities.

SECTION 1502—REQUIREMENT OF MATCHING FUNDS

Section 1502 requires that States provide matching funds in the amount of $1 for each $3 of Federal funds made available through a grant. These funds are to consist of non-Federal contributions (in cash or in kind) such as State or local dollars or State or locally-owned equipment (excluding indirect or overhead costs) and may be made directly or through donations from public or private entities. Under Section 1502(b)(3), such dollars may also consist of State Medicaid contributions provided for the coverage of preventive mammography and Pap smear screening and referral services for poor women.

In general, funds provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal government may not be counted towards meeting this requirement. Nor may the average amount of non-Federal contributions (including State Medicaid contributions) made by the State (for the two years preceding a grant award) for the purpose of carrying out breast and cervical cancer mortality prevention programs. Excluding these amounts from meeting the match requirement, should ensure that funds provided under this new Program be used to supplement, not supplant, existing State efforts to provide preventive mammography and Pap smear screening services. This Program may supplant other, general authority now being used to provide Federal assistance for breast and cervical cancer mortality prevention activities; however, the reduction or elimination of Federal assistance through other programs or mechanisms should not be interpreted as a diminution in the States' efforts.

SECTION 1503—REQUIREMENTS WITH RESPECT TO TYPE AND QUALITY OF SERVICES

Section 1503(a)(1) requires that States provide preventive screening procedures (under Section 1501(a)(1)) and appropriate referral services (under Section 1501(a)(2)) with respect to both breast and

cervical cancer, initially and throughout the entire course of a grant. The Section further requires that States expend at least 60% of their grant funds on the provision of these procedures and services. Under Section 1503(a)(3), States have up until the end of the second year of a grant to incorporate the other four activities specified in Section 1501(a) (public education (Section 1501(a)(3)); health professional training Section 1501(a)(4)); quality assurance (Section 1501(a)(5)); and program monitoring (Section 1501(a)(6)) into their breast and cervical cancer mortality prevention programs. As required under Section 1503(a)(4), no more than 40 percent of grant funds may be expended for the purpose of carrying out these four activities.

States may elect to provide or support (in accordance with the 60 percent-40 percent formula set out in Section 1503(a)) all six of the components required under Section 1501(a) from the outset of a grant period, or to phase them in during less than a two-year time frame. As each of the requirements specified under Section 1501 (a)(3) through (a)(6) is critically important to the establishment of a successful breast and cervical cancer mortality prevention program, States should take on as many of these activities as quickly as possible. It is clear, however, that all States in need of such a program (and particularly those States which may be given preference for a grant under Section 1501(b)) may not be in a position to move this rapidly. Therefore, this does not mean that any additional preference should be given to an application in which a State agrees to provide or support from the beginning of the grant period, all the activities required under Section 1501(a).

Section 1503(a)(2) requires that States include as preventive screening services, in the case of breast cancer, both a physical examination of the breasts and a mammography; and in the case of cervical cancer, both a pelvic examination and a Pap smear.

Good medical practice dictates that neither a mammography nor a Pap smear procedure be performed without an accompanying physical examination of the relevant parts of a woman's body, and these requirements are emphasized because of the over-reliance some health care professionals and State prevention programs may have on the use of advanced technology. As accurate and as effective as they are, mammograms and Pap smears do fail at times to show tumors or malignancies. Such problems (and other, equally important medical concerns as well) may be found instead through an appropriate physical examination conducted by a qualified health care professional. With respect to a breast cancer screen, such a physical examination includes a manual examination of the breasts in which both the breast and the underarm area are studied to see if any lumps can be felt or any other abnormalities (such as puckering of the skin or nipple secretion) can be observed. With respect to a cervical cancer screen, such an examination includes a manual examination of the lower abdomen, both through the vagina and the rectum, to detect any undiscovered mass that may be present. Therefore, the importance of these types of procedures is emphasized, as is the requirement that no screening test be performed unless done in conjunction with an appropriate physical examination.

Section 1503(b) requires that States substitute for mammography or the Pap smear, any superior screening technology or procedure that may become commonly available and recommended for use for cancer detection purposes. The Committee is unaware at this time of the development or distribution of any such technologies or procedures. Nonetheless, should such mechanisms come on the market, States should move immediately to use them in their own breast and cervical cancer mortality prevention programs.

Sections 1503(c) and 1503(d) require that States assure the quality of both the breast and cervical cancer screening procedures provided under their cancer mortality prevention programs. In addition, Section 1503(c) establishes quality standards with respect to mammography; and Section 1503(d) establishes such standards with respect to the Pap smear.

The quality standards established under each of these Sections reflect requirements that have been previously set in Federal law. For mammograms, these standards are identical to those created in the Medicare Catastrophic Coverage Act of 1988 (Public Law 100–360, Section 204(a)(3)) and to those which may be re-established through pending legislation to re-institute the Medicare mammography benefit. For Pap smears, these standards are identical to those provided in the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Public Law 100–578, Section 2).

These standards were adopted in an attempt to avoid any conflict among Federal programs that are (or may be) involved with these preventive health measures. And although Section 1503(e)(1) requires that the Secretary issue quality assurance guidelines that include provisions to implement these standards, it is the Committee's intention that the Secretary use (and that the States follow) any regulations or guidelines he may publish in order to carry out either the new CLIA Pap smear requirements or new Medicare mammography requirements (so long as they are similar to those first established in 1988).

While the Department of Health and Human Services has not always been prompt in issuing required regulations and guidelines, the implementation of this new Program should not be postponed because of any inaction on its part. Section 1503(e)(3) clarifies, therefore, that, regardless of the status of the guidelines required to be issued by the Secretary under Section 1503(e), the States' obligaiton to assure the quality of screening procedures conducted under this Program is not in any way diminished or otherwise altered. States are required to provide only high-quality mammography and Pap smear screening services to women participating in this Program. This requirement cannot be avoided as a result of any inaction or delay by the Department in issuing quality assurance guidelines.

SECTION 1504—ADDITIONAL REQUIRED AGREEMENTS

Section 1504(a) requires that States give priority to low-income women in the provision of screening and referral services. This requirement is of primary importance, as is the requirement that this Program (including individual State cancer mortality prevention programs) be designed to target screening mammography and

Pap smear services on those women with low incomes. Because of their income status, these women have less access to such services and, in turn, have a higher risk of going undetected for disease. The purpose of this Program is to increase the availability of these services among this population; States must, therefore, give first priority to women who come within this group.

Section 1504(b) places limitations on the amount of fees States may charge for mammography and Pap smear screening services provided under this Program. If such charges are to be included, they must be made in accordance with a publicly available schedule and they must be adjusted to reflect the income of the woman seeking services. Under Section 1504(b)(3), however, States are specifically prohibited from imposing any charge on a woman with income below the Federal poverty line.

Section 1504(c) requires that States carry out their breast and cervical cancer mortality prevention programs on a statewide basis, including making services and activities available to members of any Indian tribe or tribal organizations (as such terms are defined in Section 4 of the Indian Self-Determination and Education Assistance Act) living in the State. This requirement may be waived by the Secretary, however, if he makes a determination that compliance would result in an inefficient allocation of grant resources. Under such circumstances, States could conduct their programs with regions of a State or, in the case of the larger States (where statewide participation might be particularly difficult if resources are limited), within certain cities or towns. The Committee emphasizes, however, that the granting of a waiver of the "statewide" requirement is not to be construed to include a waiver of any other Program requirements, including those specified in Sections 1501(a)(1) and 1503(a).

Section 1504(d) requires that States seek any available payments for mammography and Pap smear screening services from other third-party payors.

Section 1504(e) limits the amount States can spend on administrative expenses associated with their breast and cervical cancer mortality prevention programs to not more than 10 percent.

Section 1504(f) prohibits States from using grant funds for the payment of inpatient hospital services.

Section 1504(g) requires that States establish appropriate fiscal control and accounting procedures to carry out their cancer mortality prevention programs.

Section 1504(h) requires that States prepare and submit any reports related to a State's grant required by the Secretary.

SECTION 1505—DESCRIPTION OF INTENDED USES OF GRANT

Section 1505 requires that States submit to the Secretary (as part of the application required under Section 1506, below), a description of the State's intended use of grant funds. This description is to include an identification of the populations, areas, and localities within the State that are in need of breast and cervical cancer mortality prevention services and activities. It is also to include information regarding the services and activities that are to be provided with grant funds as well as a discussion of the manner in

which such services and activities are to be coordinated with those provided by or through other public or non-private entities.

SECTION 1506—REQUIREMENT OF SUBMISSION OF APPLICATION

Section 1506 establishes application requirements for grant funds under this Program.

SECTION 1507—TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

Section 1507 authorizes the Secretary (either directly or indirectly through public and private entities) to provide training and technical assistance to States with respect to the planning, development and operation of their breast and cervical cancer mortality prevention programs. Section 1507 also authorizes the Secretary to provide supplies and services to States at their request in lieu of providng grant funds. Funding for these activities is authorized under Section 1509(b), described below.

SECTION 1508—EVALUATIONS AND REPORTS

Section 1508 requires that the Secretary conduct or support evaluations of all State breast and cervical cancer mortality prevention programs funded through this Program and report on such evaluations to the Congress. Such evaluations and reports are to be prepared and presented on an annual basis.

These provisions are made in order to determine the most effective and appropriate means of assuring the availability and accessibility of preventive mammography and Pap smear screening services to low-income women and of ensuring that such services are of high quality. The Secretary's annual program evaluations must be conducted and provided in a manner that allows comparison among States and that includes information on the costs associated with carrying out each of the required services and activities under Section 1501(a). The Secretary's annual report to Congress must include an assessment of the various funded State programs as well as determination of the individual States' (as compared to the Nation's) progress in meeting the Secretary's "Year 2000 Objectives" with respect to the screening of American women for breast and cervical cancer.

SECTION 1509—FUNDING

Section 1509(a) authorizes $50 million in FY 1991 and "such sums as may be necessary" in both FY 1992 and FY 1993 for grants under this Program.

Section 1509(b) requires that the Secretary withhold not more than 20 percent of the amounts appropriated each year for this Program for providing assistance under Section 1507.

Section 1509(c) limits the number of grants that may be awarded in FY 1991 to not more than fifteen.

IX. Committee Views

Breast and cervical cancer are widespread, devastating, and to a great extent preventable and curable, diseases among American

women. The Committee believes that these diseases require focused attention and funding to decrease their death rates in this country.

Information on the prevalence and severity of these diseases is given in the "Background and Need" section of this report. As the statistics show, there is a clear need for programs which focus on the early detection of breast and cervical cancer. Safe, reliable screening methods can dramatically increase the survival rate for breast cancer victims. The chances for cure in women whose cancers have been detected in the early stages are over 90 percent. Further, the 5-year survival rate for women with localized breast cancer can be almost 100 percent—as compared to 18 percent for those whose disease has spread. Comprehensive early detection programs have been shown to reduce mortality rates from breast cancer by as much as 30 percent.

The Committee believes that decreasing the numbers of women who suffer from these diseases requires funding programs at adequate levels. Small amounts of money spread over many States cannot have a significant impact on mortality. Some States have tried to support pieces of cancer mortality prevention programs on their own, such as public information campaigns or increased funding for screening. These programs have generally been small and quite limited, and cannot hope to defeat these diseases. Campaigns and outreach efforts without comparable increases in screening services may even create demands for screening that cannot be met.

In order to serve women who are not now receiving services, the Committee believes that what is needed is a targeted, well-coordinated Federal and State effort. While providing preventive breast and cervical cancer screening and referral services must be the main goal of programs supported by this bill, public health experts agree that successful programs must also include public education and outreach activities, health professional training, quality control, and appropriate monitoring and surveillance mechanisms.

In discussing quality control and surveillance, this bill makes a clear distinction between individuals who pereform the screening procedure and those who interpret it. This provision seeks to allow primary care physicians to offer screening in their offices, while radiologists interpret the mammograms. Precluding physicians from offering mammography in their offices would seriously affect women's access to the procedure. In addition, to provide adequate information, a screening mammogram should include two views of each breast, commonly referred to as a bilateral four-view technique.

States will have the flexibility under this bill to design programs which meet the needs and fill the gaps in services and support of each State. The Centers for Disease Control will work with the States and will offer technical assisstance and support in the development of programs.

Previous Congressional efforts have shown the weaknesses of depending upon existing Block Grant mechanisms to address breast and cervical cancer. In 1988, Congress amended the Preventive Health and Health Services Block Grant to include screening for breast and uterine cancer among the list of activities that could be supported by the States through the Block Grant. The intent of the

new language was to push States to address these women's health care issues more adequately.

Despite this effort, the Block Grant approach has not proven successful in promoting more focus by States on these important health problems. According to data from the Centers for Disease Control, only six States used their FY 1989 Block Grant funds to support breast and uterine cancer screening activities. The amount spent by all six of these States totaled less than $300,000.

Health officials in the States have been very supportive of this bill and its strategy of setting up a separate demonstration grant program. They do not support including breast and cervical cancer programs in the Block Grant.

The Committee feels strongly that a categorical grant program targeting breast and cervical cancer is needed. Use of the Preventive Health and Health Services Block Grant would not accomplish the same goals because its resources are spread too thin and appropriations for this grant have decreased each year. (The Block Grant received $86 million in FY88, $85 million in FY89, and ony $84 million in FY90.) While the Block Grant would allocate money to each State, no single State would receive enough resources to implement a comprehensive prevention program should it choose to do so. With no programs funded at the levels needed to demonstrate effectiveness, we would not be able to learn which early detection strategies work best.

It has been argued that we already know what works best in the area of early detection, so there is no need for such a demonstration program. The Committee believes that we do have a good idea of what types of programs should work. However, such programs have never been put to the test in the field. And there is a lot that we do not know. For example, we do not know how to motivate the women who are at highest risk for cancer to be screened. And we do not know how to best implement the comprehensive programs that we think will work. If we were certain of what to do and how to do it, the Committee believes that we would not have such high death rates for these curable, preventable diseases.

In addition, the data collection and reporting requirements of the Block Grant are minimal and do not provide for the collection of enough information to determine which programs work best and to replicate effective programs. This bill requires annual evaluations and reports to Congress.

The bill seeks to address issues of equity by requiring applying states to demonstrate need for services based on either "a substantial rate of mortality associated with breast or cervical cancer (relative to the national rate of such mortality)" or "an inadequate availability of services." By requiring a demonstration of need, the Committee intends to ensure that the need for services is the most important criterion in evaluating States' applications. While all States may be affected by these diseases, the most needy will receive funding first.

It is the intent of the Committee that every attempt be made to fund programs in both urban and rural States. Further, the intent is that these programs be implemented across the State. However, if a State demonstrates that adequate attention cannot be given to all areas of the State at once, the State will be granted a waiver of

this provision by the Secretary. This will permit these States to target limited resources to the populations at highest risk for these cancers.

Establishing a comprehensive national public health program requires some organizational planning and structure. Very few States have the infrastructure in place to take advantage of the small amounts of money that the Block Grant would provide. In a demonstration grant program, States develop effective models with the help of the CDC, and these models are disseminated to all other States seeking to implement prevention programs. This cuts down on the "bureaucracy" costs to each State, and ensures that all States are able to receive materials and support services for effective programs.

Given the large numbers of women affected by breast and cervical cancer, a high level of effort is required to reduce the morbidity and mortality rates from these diseases. This level of effort can be reached only through a targeted, comprehensive, national program aimed solely at these cancers. In those cases where resources have been available to support them, comprehensive prevention programs for breast and cervical cancers have been proven cost-effective. The Committee believes that such programs should be encouraged and supported through the national focus this bill provides.

Finally, the Committee has reviewed the Report of the Committee on Energy and Commerce of the House of Representatives (H.R. Report 101-543), which was filed on June 18, 1990 to accompany H.R. 4790, and agrees with its findings and conclusions.

X. ADDITIONAL VIEWS

Although we agree that we must work to eradicate breast and cervical cancer, we do not believe that this bill is the most efficient approach.

We are concerned that, in the last year, over 40,000 women died from breast cancer and over 6,000 died from cervical cancer—cancers that we cannot prevent but that we can treat successfully if found early enough. We know that if we can get screening services out to the community and in the clinics, we can save over 10,000 lives from breast cancer alone. Unfortunately, the bill that has been reported out of the committee does not accomplish this basic goal.

First, the bill focuses the effort in only 15 states, leaving the remaining 35 with no additional funds or additional services for low-income women.

Second, we are concerned with the time required to get funds out to projects funded under the categorical approach. It has been over nine months since the current appropriation was made for a program that is similar in nature to that proposed in this bill. At the time the bill was reported out of committee, those funds had not yet been awarded. During that nine-month period, this nation was three-quarters of the way toward another 46,000 deaths from breast and cervical cancer.

Third, the bill as reported contains a matching requirement. Those states in greatest need are frequently those least likely able to provide additional dedicated state and local funds to meet the match requirements.

Fourth, the committee already authorizes a broad approach to providing health services to eligible American women, through Title X programs, Community and Migrant Health Centers, and, most important, the current Prevention Block Grant. When we reviewed the provisions of the block grant, we were impressed with its existing parallel structure to S. 2283 as reported out by the committee. We should not authorize a duplicate categorical program that will compete for scarce funding when existing delivery systems could be used to achieve these critical objectives.

In conclusion, we know how to screen for breast and cervical cancer. We have proven technology for the screening. We have several delivery systems already in place to provide the service to low-income women. And, we have a way to get money out to the state health departments quickly with minimum federal overhead. The problem is not one of applying known technology or demonstrating that screening works; it is one of motivating people to use the technology and to avail themselves of screening services.

ORRIN HATCH.
STROM THURMOND.
DAVE DURENBERGER.
THAD COCHRAN.

XI. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

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TITLE XIV—SAFETY OF PUBLIC WATER SYSTEMS

[For Text of This Title See Volume III]

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TITLE XV—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

SEC. 1501. ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES.

(a) In General.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) Preferences in Making Grants.—In making grants under subsection (a), the Secretary shall give preference to any State in which—

(1) there is a substantial rate of mortality associated with breast or cervical cancer (relative to the national rate of such mortality); and

(2) there is an inadequate availability of services or activities described in such subsection.

(c) Geographic Distribution of Grants.—In making grants under subsection (a), the Secretary shall ensure that the grants are

equitably distributed among the principal geographic regions of the United States.

(d) GRANT AND CONTRACT AUTHORITY OF STATES.—A State receiving a grant under subsection (a) may expend the grant to carry out the purpose described in such subsection through grants to, and contracts with, public or nonprofit private entities.

SEC. 1502. REQUIREMENT OF MATCHING FUNDS.

(a) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

(1) IN GENERAL.—Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a).

SEC. 1503. REQUIREMENTS WITH RESPECT TO TYPE AND QUALITY OF SERVICES.

(a) REQUIREMENT OF PROVISION OF ALL SERVICES BY DATE CERTAIN.—The Secretary may not make a grant under section 1501 unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) is provided; and

(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) USE OF IMPROVED SCREENING PROCEDURES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c) QUALITY ASSURANCE REGARDING SCREENING FOR BREAST CANCER.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will assure the quality of any screening procedure for breast cancer conducted pursuant to such section and, in the case of mammography, will provide that—

(1) the equipment used to perform the mammography will be specifically designed for mammography and will meet appropriate radiologic standards for mammography;

(2) the mammography will be performed by an individual who—

(A) is licensed by a State to perform radiological procedures; or

(B) is certified as qualified to perform radiological procedures by an appropriate organization;

(3) the results of the mammography will be interpreted by a physician who—

(A) is certified as qualified to interpret radiological procedures by an appropriate board; or

(B) is certified as qualified to interpret screening mammography procedures by an appropriate program for assuring the qualifications of the individual with respect to such interpretations; and

(4) with respect to the first screening mammography performed on a woman for which payment is made pursuant to section 1501(a), there are satisfactory assurances that the results of the mammography will be placed in permanent medical records maintained with respect to the woman.

(d) QUALITY ASSURANCE REGARDING SCREENING FOR CERVICAL CANCER.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will assure the quality of any screening procedure for cervical cancer conducted pursuant to such section and, in the case of the pap smear (or other cytological screening procedure replacing the pap smear pursuant to subsection (b)), will provide—

(1) the maximum number of cytology slides that any individual may screen in a 24-hour period;

(2) requirements that a clinical laboratory maintain a record of—

(A) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory; and

(B) the number of hours devoted during each 24-hour period to screening cytology slides by such individual;

(3) criteria for requiring rescreening of cytological preparations, such as—

(A) random rescreening of cytology specimens determined to be in the benign category;

(B) focused rescreening of such preparations in high risk groups; and

(C) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available;

(4) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions;

(5) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides;

(6) requirements that all cytological screening be done on the premises of an appropriately qualified laboratory;

(7) requirements for the retention of cytology slides by laboratories for appropriate periods of time; and

(8) requirements of periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(e) ISSUANCE BY SECRETARY OF GUIDELINES WITH RESPECT TO QUALITY OF MAMMOGRAPHY AND CYTOLOGICAL SERVICES.—

(1) IN GENERAL.—The Secretary shall establish guidelines for assuring the quality of any mammography and cytological screening procedure conducted pursuant to section 1501(a). Such guidelines with respect to mammography shall include the provisions of paragraphs (1) through (4) of subsection (c), and such guidelines with respect to cytological screening procedures shall include the provisions of paragraphs (1) through (8) of subsection (d).

(2) APPLICABILITY WITH RESPECT TO GRANTS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the State will, with respect to any mammography or cytological screening procedure conducted pursuant to such section, ensure that the procedure is conducted in accordance with the guidelines issued by the Secretary under paragraph (1).

(3) RESPONSIBILITY OF STATES IN ABSENCE OF GUIDELINES.—With respect to circumstances in which a State receives a grant under section 1501 before the issuance of guidelines under paragraph (1), this subsection may not be construed to affect in such circumstances the obligation of the State pursuant to subsection

(a)(1) to provide for screening procedures and referrals or the obligations under subsections (c) and (d) with respect to providing for quality in the screening procedures.

SEC. 1504. ADDITIONAL REQUIRED AGREEMENTS.

(a) PRIORITY FOR LOW-INCOME WOMEN.—The Secretary may not make a grant under section 1501 unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a).

(b) LIMITATION ON IMPOSITION OF FEES FOR SERVICES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(c) STATEWIDE PROVISION OF SERVICES.—

(1) IN GENERAL.—The Secretary may not make a grant under section 1501 unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

(2) WAIVER.—The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a).

(d) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under section 1501 unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(f) RESTRICTIONS ON USE OF GRANT.—The Secretary may not make a grant under section 1501 unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(g) RECORDS AND AUDITS.—The Secretary may not make a grant under section 1501 unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(h) REPORTS TO SECRETARY.—The Secretary may not make a grant under section 1501 unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

SEC. 1505. DESCRIPTION OF INTENDED USES OF GRANT.

The Secretary may not make a grant under section 1501 unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a); and

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities.

SEC. 1506. REQUIREMENT OF SUBMISSION OF APPLICATION.

The Secretary may not make a grant under section 1501 unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505, and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title.

SEC. 1507. TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.

(a) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

(1) IN GENERAL.—Upon the request of a State receiving a grant under section 1501, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 to the State involved by an amount equal to the costs of

detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

SEC. 1508. EVALUATIONS AND REPORTS.

(a) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 1501.

(b) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a), and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title as the Secretary determines to be appropriate.

SEC. 1509. FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $50,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(b) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507.

(c) LIMITATION ON NUMBER OF INITIAL GRANTS.—For fiscal year 1991, the Secretary may not make more than 15 grants under section 1501.

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